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Lareau

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(54) **SELECTIVE SURFACE MODIFICATION OF CATHETER TUBING**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 13/118,111, filed on May 27, 2011, now Pat. No. 8,777,928, which is a continuation of application No. 10/987,010, filed on Nov. 12, 2004, now Pat. No. 7,951,116.

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B29C 47/00 (2006.01)
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CPC ***A61M 25/0045*** (2013.01); ***A61M 25/0009*** (2013.01); ***A61M 25/0054*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 25/0045; A61M 25/0009; A61M 2025/0047; A61M 2025/0046; A61M 2025/0004
USPC 264/176.1; 604/264, 525
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,561,569 A 7/1951 Flynn
2,616,126 A 11/1952 Merck et al.
(Continued)

FOREIGN PATENT DOCUMENTS

DE 3917523 A1 12/1990
DE 19651904 A1 6/1998
(Continued)

OTHER PUBLICATIONS

All non-published literature documents and foreign patent documents have been previously uploaded in parent U.S. Appl. No. 13/118,111, filed May 27, 2011 and U.S. Appl. No. 10/987,010, filed Nov. 12, 2004.
(Continued)

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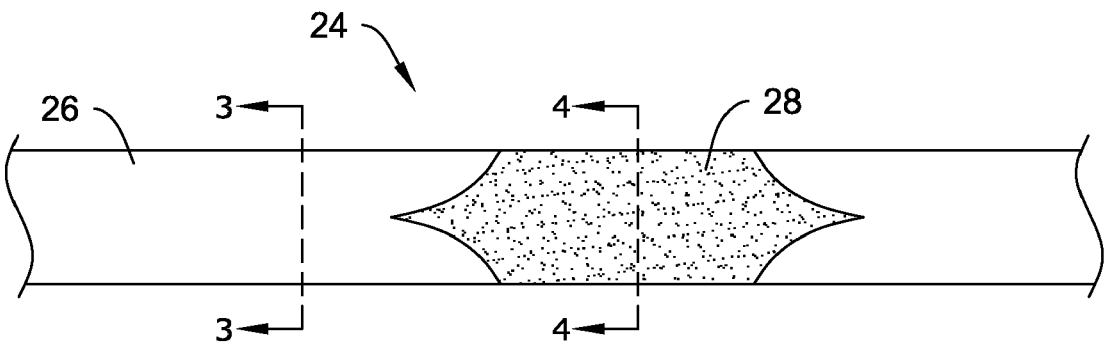
(57) **ABSTRACT**

A catheter shaft and methods for making and using the same. The catheter shaft may include a core portion, a cap portion, and one or more lumens. The cap portion may be disposed on or over a section of the core portion and define a region with a different exterior or interior surface characteristic. For example, the cap portion may define a lubricious region along the catheter shaft. Manufacturing the catheter shaft may include a modified co-extrusion process that incorporates a flow valve on at least one of the material supply lines so that the supply line can be regulated by a user.

20 Claims, 7 Drawing Sheets



(51) **Int. Cl.**

B29C 47/06	(2006.01)
B29C 47/08	(2006.01)
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B29C 47/28	(2006.01)
B29C 47/56	(2006.01)
B28B 3/20	(2006.01)

(52) **U.S. Cl.**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

2,940,126	A		6/1960	Sheridan
3,015,355	A		1/1962	Humphrey
3,193,878	A		7/1965	Corbett
3,404,203	A		10/1968	Donald
3,712,782	A		1/1973	Burlis
3,724,985	A		4/1973	Burlis et al.
3,752,617	A		8/1973	Burlis et al.
3,824,479	A		7/1974	Alger
3,891,374	A		6/1975	Ninomiya et al.
3,944,641	A		3/1976	Lemelson
4,005,166	A		1/1977	Quick
4,138,457	A		2/1979	Rudd et al.
4,209,476	A		6/1980	Harris
4,250,072	A		2/1981	Flynn
4,272,466	A		6/1981	Harris
4,276,250	A		6/1981	Satchell et al.
4,277,432	A		7/1981	Woinowski
4,283,447	A		8/1981	Flynn et al.
4,293,294	A		10/1981	Rasmussen et al.
4,330,497	A		5/1982	Agdanowski et al.
4,332,759	A		6/1982	Ide
4,430,282	A		2/1984	Stack
4,430,283	A		2/1984	Burnett et al.
4,430,698	A		2/1984	Harris
4,447,239	A		5/1984	Krutten
4,657,024	A		4/1987	Coneys
4,729,662	A		3/1988	O'Brien
4,734,240	A		3/1988	Chung
4,783,647	A		11/1988	Wood
4,786,181	A		11/1988	O'Brian
4,790,970	A		12/1988	Kurth et al.
4,830,805	A		5/1989	Kousai et al.
4,838,778	A		6/1989	Becker et al.
4,858,139	A		8/1989	Wirtz
4,888,146	A		12/1989	Dandeneau
4,919,605	A		4/1990	Kousai et al.
4,956,143	A		9/1990	McFarlane
4,981,478	A		1/1991	Evard et al.
4,990,143	A		2/1991	Sheridan
5,059,375	A		10/1991	Lindsay
5,063,018	A		11/1991	Fontirroche et al.
5,085,649	A		2/1992	Flynn
5,125,913	A		6/1992	Quackenbush
5,128,077	A		7/1992	Stevenson et al.
5,156,785	A		10/1992	Zdrahala
5,156,857	A		10/1992	Wang et al.
5,215,614	A		6/1993	Wijkamp et al.
5,240,537	A		8/1993	Bodicky
5,248,305	A		9/1993	Zdrahala
5,312,356	A	*	5/1994	Engelson et al. 604/164.13
5,374,245	A		12/1994	Mahurkar
5,409,644	A		4/1995	Martin et al.
5,456,674	A		10/1995	Bos et al.
5,498,377	A		3/1996	Ozaki et al.
5,505,887	A		4/1996	Zdrahala et al.
5,520,870	A		5/1996	Allan et al.
5,531,721	A	*	7/1996	Pepin et al. 604/525
5,533,985	A		7/1996	Wang
5,542,937	A	*	8/1996	Chee et al. 604/523
5,589,236	A		12/1996	Harvey et al.
5,622,665	A		4/1997	Wang
5,639,409	A		6/1997	Van Muiden
5,695,789	A		12/1997	Harris
5,725,814	A		3/1998	Harris
5,734,240	A		3/1998	Janca et al.
5,738,742	A		4/1998	Stevens
5,755,704	A	*	5/1998	Lunn 604/527
5,836,925	A		11/1998	Soltesz
5,843,539	A		12/1998	Harvey et al.
5,851,477	A		12/1998	Halgren et al.
5,868,718	A		2/1999	Pepin et al.
5,882,741	A		3/1999	Rubin et al.
5,947,940	A		9/1999	Beisel
5,951,494	A		9/1999	Wang et al.
5,968,438	A		10/1999	Imaizumi
5,984,657	A		11/1999	Bentivoglio
6,030,369	A		2/2000	Engelson et al.
6,048,484	A		4/2000	House et al.
6,103,037	A		8/2000	Wilson
6,135,992	A		10/2000	Wang
6,165,166	A		12/2000	Samuelson et al.
6,171,295	B1		1/2001	Garabedian et al.
6,280,423	B1		8/2001	Davey et al.
6,319,228	B1	*	11/2001	Kastenhofer 604/96.01
6,436,056	B1		8/2002	Wang et al.
6,458,069	B1		10/2002	Tam et al.
6,530,765	B1		3/2003	Zdrahala et al.
6,663,614	B1		12/2003	Carter
6,776,945	B2		8/2004	Chin et al.
7,163,523	B2	*	1/2007	Devens et al. 604/96.01
7,662,144	B2		2/2010	Chan et al.
2002/0119264	A1		8/2002	Wang
2003/0009151	A1		1/2003	Wang
2003/0030165	A1		2/2003	Centell et al.
2004/0064130	A1		4/2004	Carter
2004/0210211	A1		10/2004	Devens, Jr. et al.
2004/0243102	A1		12/2004	Berg et al.
2005/0115624	A1	*	6/2005	Walak 138/139
2005/0124976	A1	*	6/2005	Devens et al. 604/523
2006/0051535	A1		3/2006	Arney et al.
2006/0106351	A1	*	5/2006	Lareau 604/264

FOREIGN PATENT DOCUMENTS

EP	0417865	A1	3/1991
EP	0437291	A1	7/1991
EP	0528181	A1	2/1993
EP	0618059	A1	10/1994
EP	0662385	A1	7/1995
EP	0992335	A2	4/2000
JP	6015004	A	1/1994
JP	9309139	A	12/1997
JP	2001309533	A	11/2001
WO	9325372	A1	12/1993
WO	9524304	A1	9/1995
WO	9529051	A1	11/1995
WO	9600100	A1	1/1996
WO	9626671	A1	9/1996
WO	9626825	A1	9/1996
WO	9736629	A1	10/1997
WO	0001420	A2	1/2000

OTHER PUBLICATIONS

Lusignea, R., "Flexible Multilayer Packaging with Oriented LCP Barrier Layer," TAPPI Proceedings, (1998) pp. 889-899.

* cited by examiner

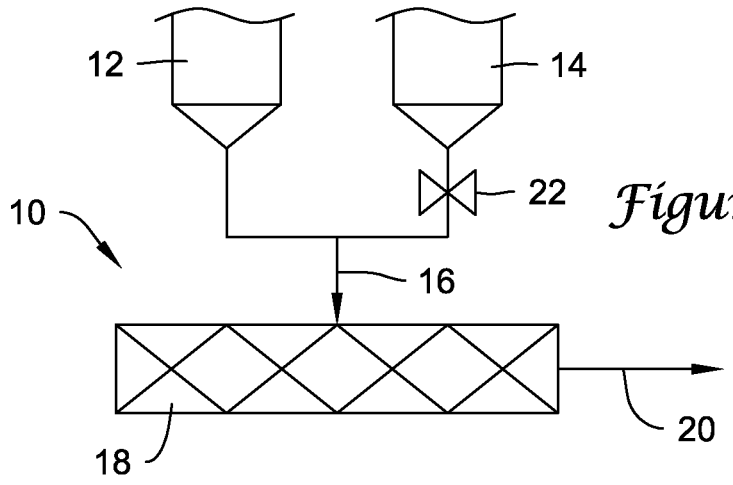


Figure 1

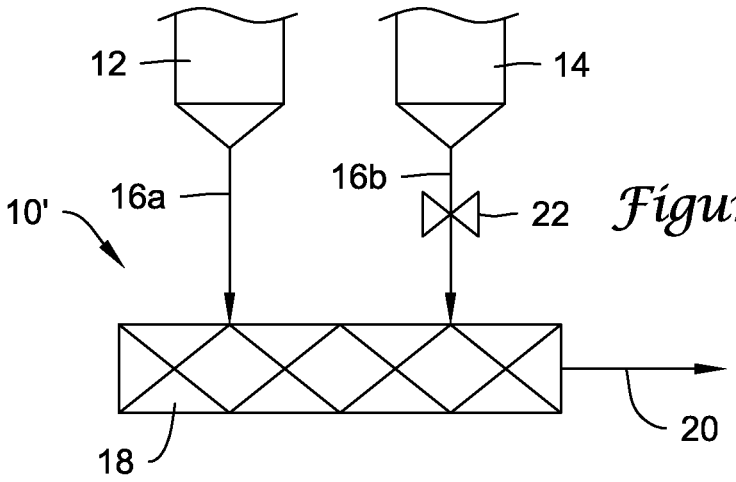
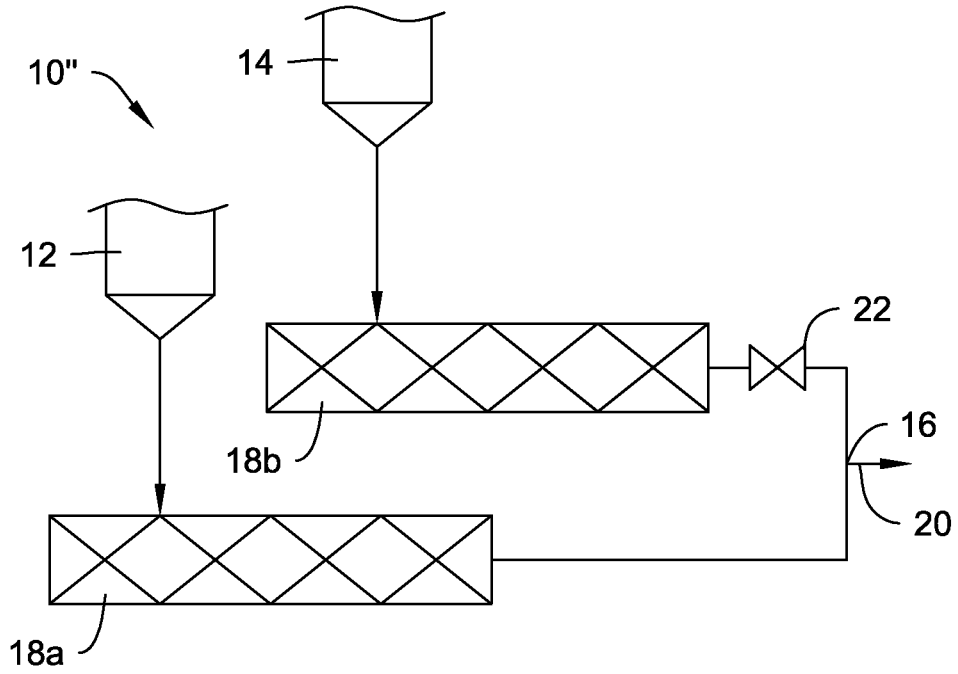


Figure 1A



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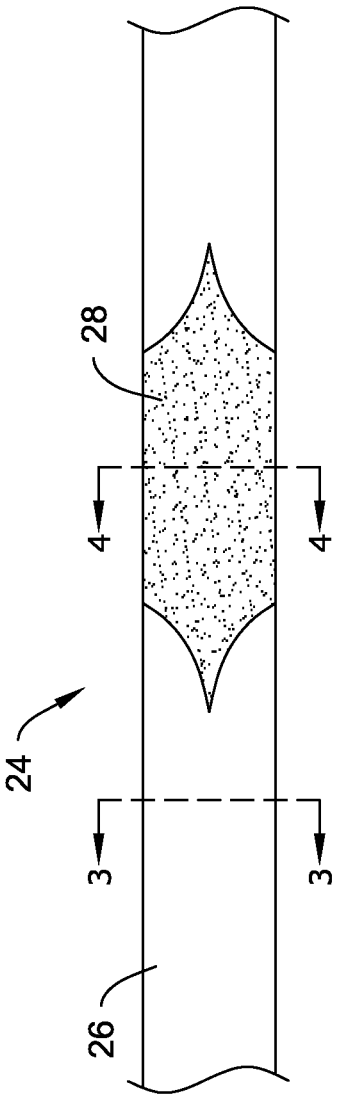

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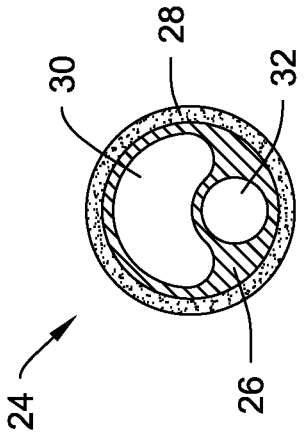


Figure 4

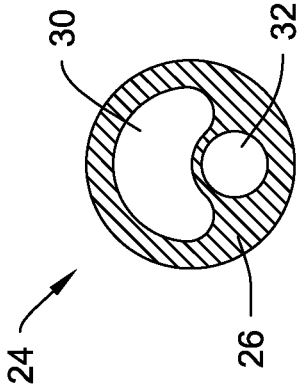


Figure 3

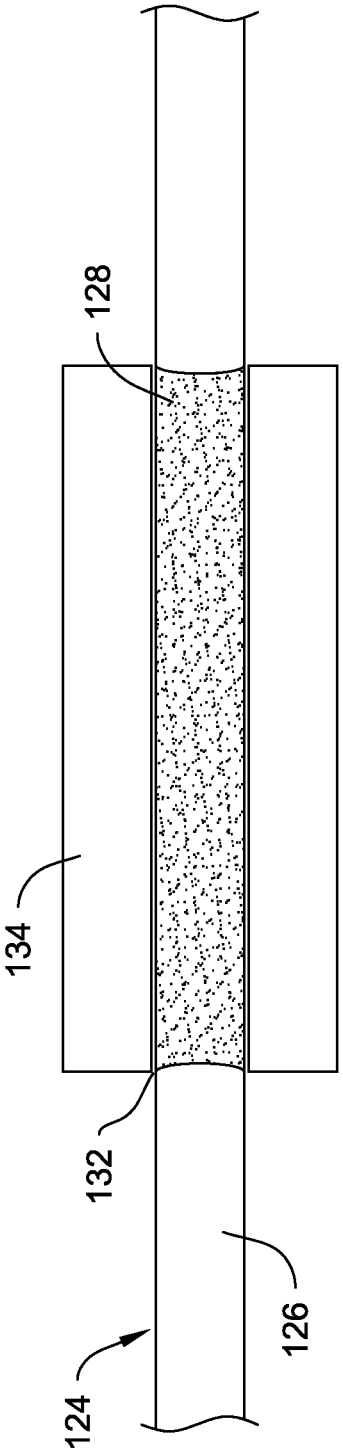


Figure 5

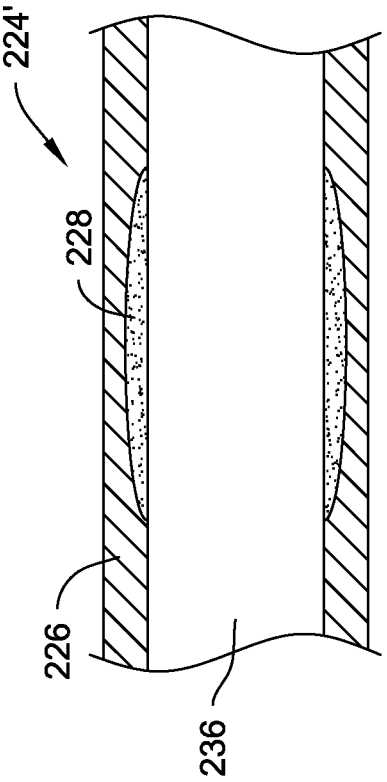


Figure 6B

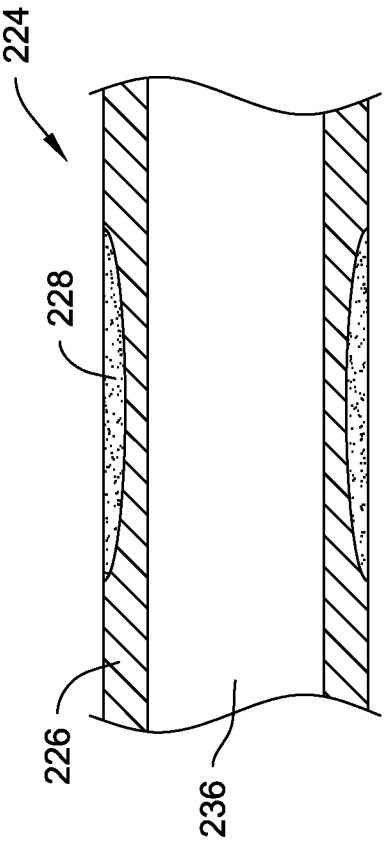


Figure 6A

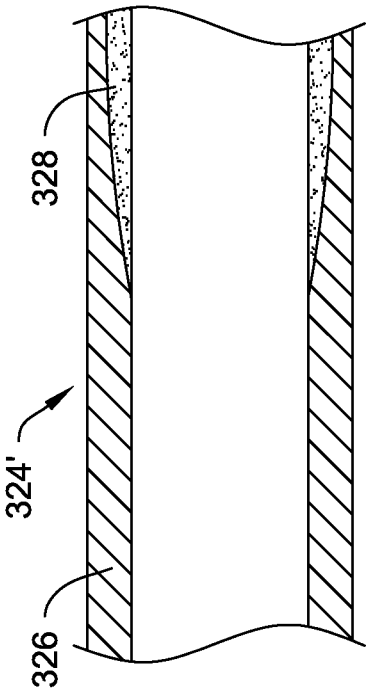


Figure 7B

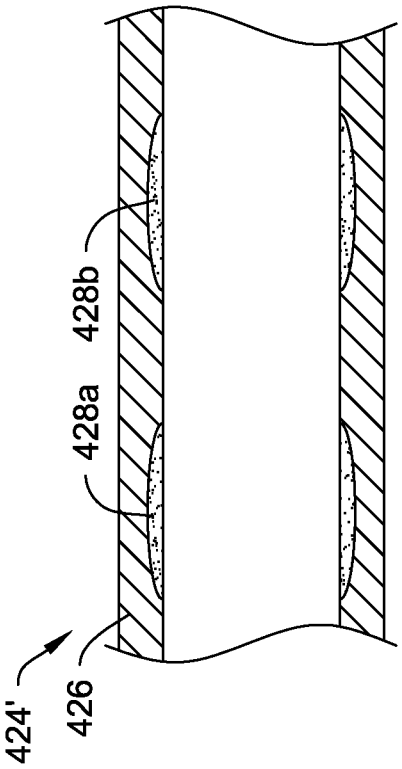


Figure 8B

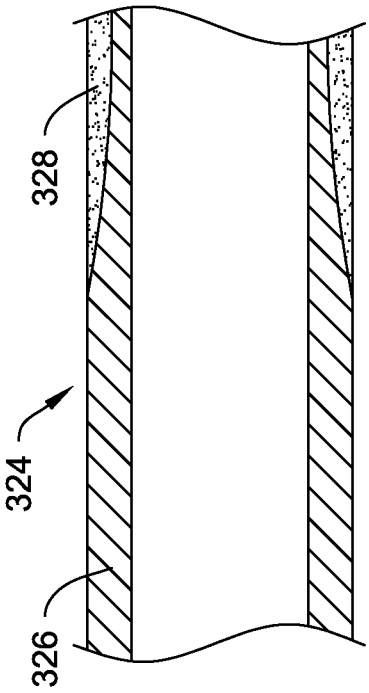


Figure 7A

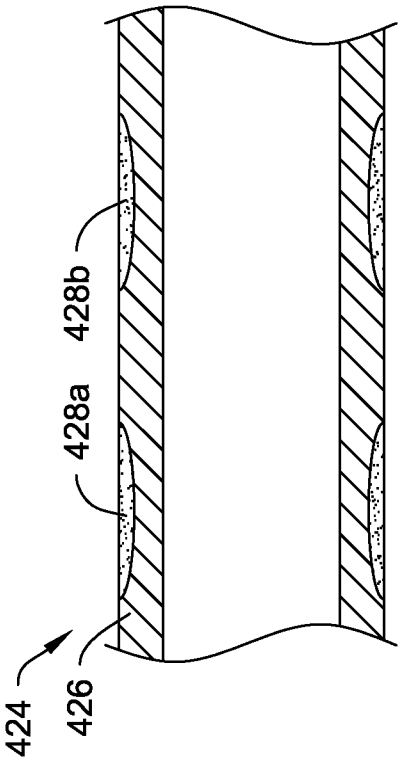
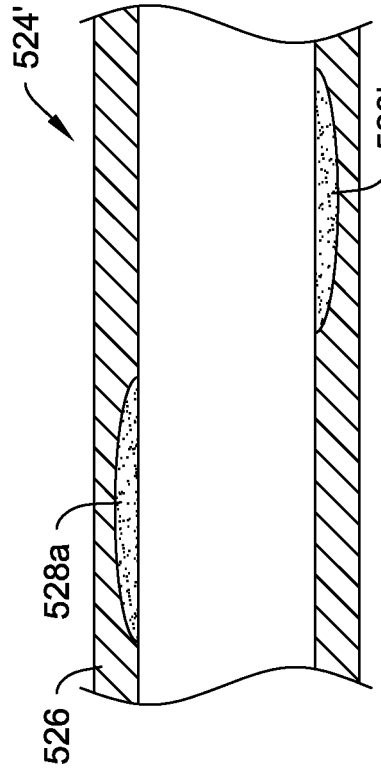


Figure 8A



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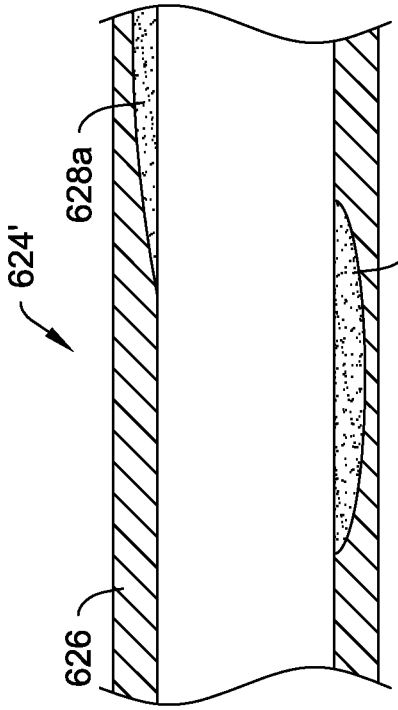


Figure 10B

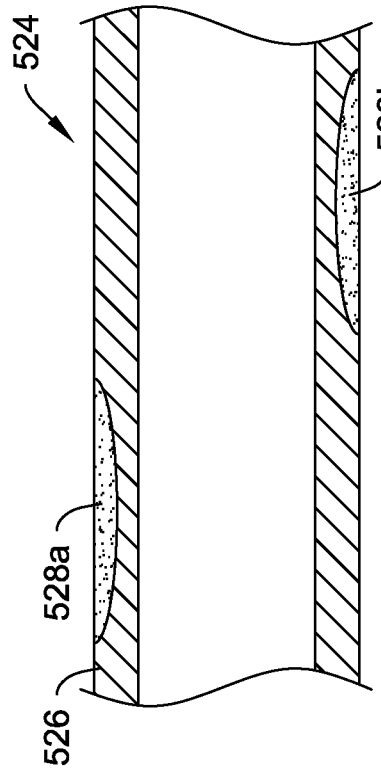


Figure 9A

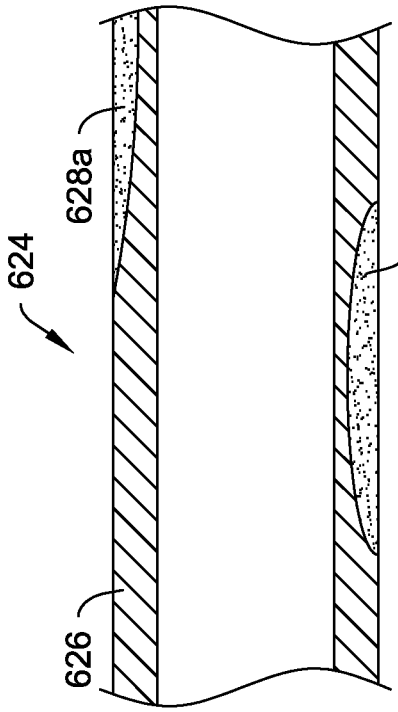
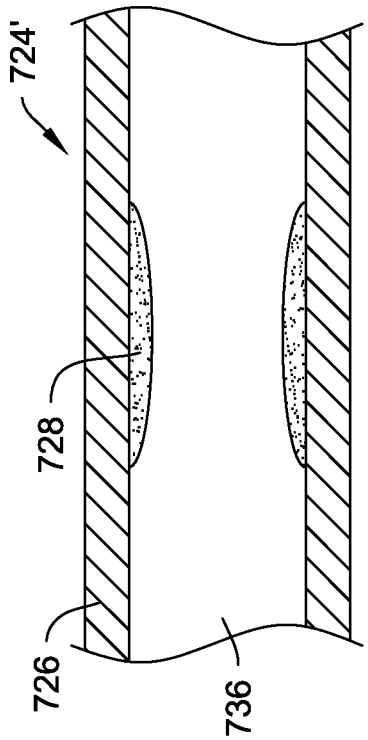


Figure 10A



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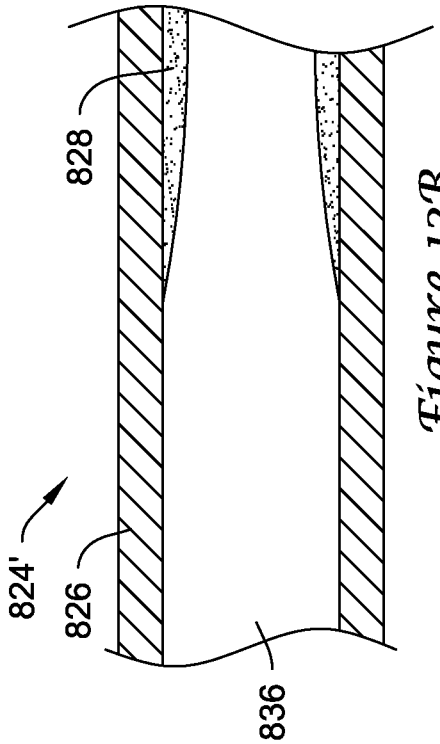

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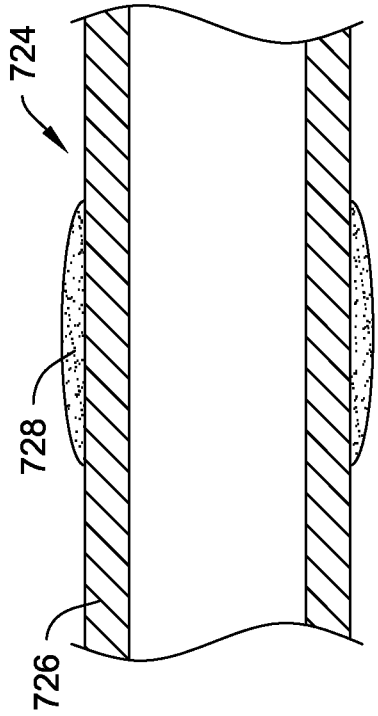

Figure 11A

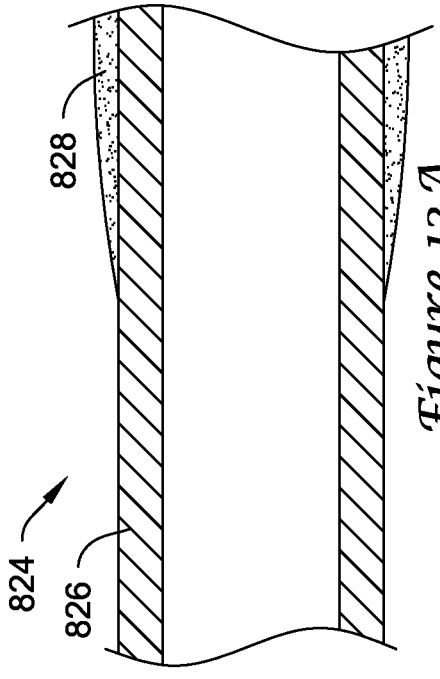

Figure 12A

SELECTIVE SURFACE MODIFICATION OF CATHETER TUBING

RELATED APPLICATIONS

This application is a continuation of co-pending U.S. application Ser. No. 13/118,111, filed May 27, 2011, which is a continuation of U.S. application Ser. No. 10/987,010, filed Nov. 12, 2004, now U.S. Pat. No. 7,951,116, the entire disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention pertains to medical devices and methods for making and using medical devices. More particularly, the present invention pertains to catheter shafts with surface modifications and/or changes in surface characteristics as well as methods for making catheter shafts with surface modifications.

BACKGROUND

A wide variety of medical devices have been developed. At least some of these devices are designed to pass through an opening or lumen in the body or through a lumen or channel (e.g., a working channel) in another medical device. For example, the device may comprise a catheter (e.g., therapeutic, diagnostic, or guide catheter), an endoscopic device, a laproscopic device, an embolic protection device, and the like, or any other suitable device. Among these known devices, each has certain advantages and disadvantages. There is an ongoing need to provide alternative designs and methods of making and using new and improved medical devices.

BRIEF SUMMARY

The invention provides design, material, and manufacturing method alternatives for catheters, catheter shafts, and the like. In at least some embodiments, a catheter shaft may include a generally tubular catheter shaft. The catheter shaft may include a core portion, a cap portion, and one or more lumens defined therein. The cap portion may be disposed on or over a section of the core portion and define a region with a different exterior or interior surface characteristic. For example, the cap portion may define a lubricious region along the catheter shaft. Some of the other features of this catheter shaft and others like it are described in more detail below.

Manufacturing the catheter shaft may include a modified co-extrusion process. The modified process incorporates a flow valve on at least one of the material supply lines so that the supply line can be regulated by a user. For example, a user may vary the amount of material from an extruder to be used in the production of the catheter shaft anywhere between 0-100% of the total output. This allows the catheter shaft to be manufactured with different characteristics (e.g., surface characteristics) without the need for additional coating, fusing, or attachment steps. Some other features of this method and other methods like it are described in more detail below.

The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present invention. The Figures, and Detailed Description which follow, more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

FIG. **1** is a schematic overview depicting an example co-extrusion apparatus;

FIG. **1**A is a schematic overview depicting another example co-extrusion apparatus;

FIG. **1**B is a schematic overview depicting another example co-extrusion apparatus;

FIG. **2** is a side view of an example catheter shaft;

FIG. **3** is a cross-sectional view of a portion of the catheter shaft shown in FIG. **2**;

FIG. **4** is a cross-sectional view of another portion of the catheter shaft shown in FIG. **2**;

FIG. **5** is a partial cross-sectional side view of an example catheter shaft disposed in the working channel of an endoscope;

FIG. **6**A is a cross-sectional side view of another example catheter shaft;

FIG. **6**B is a cross-sectional side view of another example catheter shaft;

FIG. **7**A is a cross-sectional side view of another example catheter shaft;

FIG. **7**B is a cross-sectional side view of another example catheter shaft;

FIG. **8**A is a cross-sectional side view of another example catheter shaft;

FIG. **8**B is a cross-sectional side view of another example catheter shaft;

FIG. **9**A is a cross-sectional side view of another example catheter shaft;

FIG. **9**B is a cross-sectional side view of another example catheter shaft;

FIG. **10**A is a cross-sectional side view of another example catheter shaft;

FIG. **10**B is a cross-sectional side view of another example catheter shaft;

FIG. **11**A is a cross-sectional side view of another example catheter shaft;

FIG. **11**B is a cross-sectional side view of another example catheter shaft;

FIG. **12**A is a cross-sectional side view of another example catheter shaft; and

FIG. **12**B is a cross-sectional side view of another example catheter shaft.

DETAILED DESCRIPTION

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings illustrate example embodiments of the claimed invention.

FIG. **1** is a schematic view of an example extrusion apparatus **10** that may be used to manufacture a catheter, catheter shaft, or other similar medical device. Apparatus **10** may include a first feed hopper or reservoir **12** and a second feed hopper or reservoir **14**. In at least some embodiments, the two feed hoppers **12**/**14** may combine at a feed pipe or cross-head **16** and feed an extruder **18**. The output of extruder **18** is indicated by reference number **20**. Feed hoppers **12**/**14** may hold different manufacturing materials so that the modified co-extrusion process can produce a multi-layered or multi-material device such as shaft **24** as best seen in FIG. **2**. In some

embodiments, additional feed hoppers or extruders may be included that hold and supply additional materials. Output **20** may be any suitable medical device (or a precursor thereto) such as a catheter (e.g., angioplasty, stent delivery, therapeutic, diagnostic, or guide catheter) or catheter shaft, an endoscopic device, a laproscopic device, an embolic protection device, or any other suitable device.

Apparatus **10** differs from other co-extrusion devices in that it includes a flow valve **22** coupled thereto. In at least some embodiments, flow valve **22** is positioned so that it can regulate the flow of material from feed hopper **14**. Of course, flow valve **22** could alternatively be used to regulate feed hopper **12** (and/or any other feed hopper that may be present) or an additional flow valve **22** can be used to regulate feed hopper **12** in concert with the valve **22** regulating the flow from feed hopper **14**. Flow valve **22** can be configured so that it can meter the flow from feed hopper **14** so that the supply of material from feed hopper **14** can be completely stopped (i.e., 0% flow), completely open or continuously flowing (i.e., 100% flow), or anywhere in between. In at least some embodiments, at least one material (e.g. the material from feed hopper **12**) constantly feeds cross-head **16** while the other material (e.g., the material from feed hopper **14**) is regulated as described above. Accordingly, apparatus **10** allows, for example, output **20** to constantly include one material (e.g., the material supplied by feed hopper **12**) and include a variable amount of a second material (e.g., the material supplied by feed hopper **14** and regulated by valve **22**). This includes the ability to apply material from feed hopper **14** to multiple, discrete sections of the resultant device.

Valve **22** may be similar to other typical valves. For example, valve **22** may be a simple on/off diverting valve or something more complicated like a computer programmed proportional shut off valve. Either way, valve **22** may utilize a pneumatic, hydraulic, or other standard transfer means for controlling flow. In some embodiments, valve **22** diverts material within or away from extruder **18**. Alternatively, valve **22** may be part of a closed extrusion system that creates a "compression chamber" where materials are contained and reused. In general, valve **22** may be adjusted between a number of positions. For example, valve **22** may have a first configuration or setting that substantially blocks the flow of material from second hopper **14** to extruder **18** and a second configuration that allows the material in second hopper **14** to flow to extruder **18**. A number of additional settings or configurations may also exist that alter the amount of material that is permitted to flow from second hopper **14** to extruder **18**.

This modified co-extrusion process may be desirable for a number of reasons. For example, because the supply from feed hopper **14** is regulated by valve **22** for the cap portion of a shaft (not shown in FIGS. **1** and **1**A, please see, for example, cap portion **28** in FIG. **2**), there is less waste than in other intermittent co-extrusions where larger volumes of materials are displaced from the extruder and become waste. This savings of material can be significant, especially if higher cost materials are used, such as polymers doped with radiopaque fillers (including precious metals). Another desirable feature may be that a single process can be used to manufacture a product having a variable material composition. In fact, apparatus **10** allows for the combination of extruding and so-called "coating" or "capping" steps. For example, feed hopper **12** may be used to supply the "core" material and feed hopper **14** may be used to coat or cap the core. In addition, output **20** may produce complex products including multi-lumen tubing that is coated internally or externally. This may be desirable because the process reduces any trepidation regarding the possibility of melting the tube, thereby collapsing any or all of the lumens, during a potentially heat-intensive subsequent coating and/or sleeving operation. This feature may also be advantageous when it is desirable to coat one or more portions of the core, for example, to impart a desired surface characteristic to a selective portion or portions of a device. Other desirable features may include an improved interface between shaft **24** sections due to the fact that fusing or bonding individual sections is no longer required, fewer method steps to produce a finished product (no need to connect tube section via adhesive bonding, thermal bonding, welding, and the like), increased strength at the interface between shaft sections because of the continuous and seamless transition between sections, etc.

It should be noted that at least some embodiments utilize flow valve **22** for only one of the two illustrated hoppers **12**/**14**. Accordingly, using flow valve **22** to completely stop the flow from feed hopper **14** would result in output **20** coming from feed hopper **12**. Similarly, using flow valve **22** open 100% would result in output **20** comprising a combination of the materials from feed hopper **12** and hopper **14**. The proportions of materials coming from hopper **12** and hopper **14** can vary depending on the set up of apparatus **10** and the setting of valve **22**. This embodiment is also distinct from other co-extrusion devices where only a constant flow of multiple materials or a transition from 100% of a first material to 100% of a second material (abruptly or gradually) is possible.

Apparatus **10** depicts the flow of materials from hoppers **12**/**14** (including the metered control from hopper **14**) into a common cross-head **16**. This need not be the only suitable arrangement, because other flow patterns are contemplated. For example, FIG. **1**A is a schematic view of another example extrusion apparatus **10'**. Apparatus **10'** is similar to apparatus **10** except that first hopper **12** and second hopper **14** feed into their own individual feed pipes **16***a*/*b* and flow valve **22** regulate flow in feed pipe **16***b*. This drawing indicates that the modified co-extrusion process that is disclosed herein can also vary in the way materials loaded in feed hoppers **12**/**14** are delivered to extruder **18**. A number of additional variations in the setup of apparatus **10'** (and apparatus **10**) are contemplated and are thought to be well within the spirit and scope of the invention.

FIG. **1**B is a schematic view of another example extrusion apparatus **10"**. Apparatus **10"** is similar to apparatus **10**/**10'** except that first hopper **12** and second hopper **14** are each coupled to their own extruders (i.e., extruders **18***a* and **18***b*, respectively), and then extruders **18***a*/**18***b* feed into a common cross-head **16**. Flow valve **22** regulates the flow of material from one of the extruders (e.g., extruder **18***b*) into the common cross-head. Of course, flow valve **22** could just as easily regulate the flow from extruder **18***a* or a second flow valve **22** may be utilized so that the flow can be regulated from both extruder **18***a* and **18***b*. This drawing indicates that the modified co-extrusion process that is disclosed herein can also vary in the way materials from a plurality of sources (e.g., extruders **18***a*/**18***b*) are delivered to a common cross-head **16**. Output **20** from apparatus **10"**, therefore, includes material from feed hopper **12** and extruder **18***a* and a regulated amount of material from feed hopper **12** and extruder **18***b*, depending on the extent to which valve **22** is open or closed. A number of additional variations in the setup of apparatus **10"** (and apparatus **10** and **10'**) are contemplated and are thought to be well within the spirit and scope of the invention. For example,

additional feed hoppers and extruders may be added that can also feed into cross-head **16** or be arranged in parallel to cross-head **16**.

FIG. **2** is a side view of an example catheter shaft **24** that may be manufactured using apparatus **10**, apparatus **10'**, or any of the contemplated variations of these devices. Shaft **24** may include a core portion **26** and a cap portion **28**. In at least some embodiments, core portion **26** is manufactured by extrusion of the materials supplied from feed hopper **12** or another "unregulated" or "unvalved" hopper or extruder. Cap portion **28** can be manufactured by regulated co-extrusion of the materials supplied from hopper **14** or another hopper or extruder that includes valve **22**. Thus, manufacturing of shaft **24** can include an extrusion similar to what is described above where valve **22** is used to specify the desired location(s) and lengths for cap portion **28**. The embodiment shown depicts that cap portion **28** can be positioned at a centralized location of shaft **24** (i.e., away from the ends of shaft **24**). Thus, some regions of shaft **24** may include only core portion **26**, as best seen in cross-section at FIG. **3**, and other regions of shaft **24** may include core portion **26** capped with cap portion **28**, as best seen in cross-section at FIG. **4**.

The materials used to manufacture shaft **24** can vary considerably. For example, core portion **26** and cap portion **28** may be each made from a polymer such as a thermoplastic (including neat and filled thermoplastic resins). Some examples of suitable polymers may include thermoplastic urethane elastomers, polyurethane, polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, polyether block amide (PEBA, for example, available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), polyethylene (PE) including linear low, low, medium, and high density polyethylene, polyethylene terephthalate (PET), other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like.

Generally, the materials selected for core portion **26** are selected based on their flexibility characteristics (such as being sufficiently stiff) or other physical characteristics that are desirable for the intended application of shaft **24**. The materials selected for cap portion **26** may be selected so as to impart a change in the exterior or interior surface of shaft **24**. For example, the materials selected for cap portion **28** may define a region of shaft **24** that has a high hardness or is lubricious. In addition, because of the flow regulation achievable through the use of valve **22**, the desired surface characteristic (for example, lubricity) can be positioned only where (and/or every place) it is needed or desired. Lubricious coatings improve steerability and improve the ability of shaft **24** to pass through or otherwise be moveable within another device such as the working channel of an endoscope. Thus, the addition of cap portion **28** may define a region on shaft **24** that is optimized for tracking in a working channel of an endoscope. In addition, the addition of cap portion **28** internally may define a region optimized for deploying coils or for guidewire tracking. Another desirable application for cap portion **28** may be defining a region along shaft **24** that is configured for attaching an angioplasty balloon or another object. Suitable lubricious polymers are well known in the art and may include silicone co-polymers and the like, hydrophilic polymers, high-density polyethylene (HDPE), polytetrafluoroethylene (PTFE), fluoropolymers, polyarylene oxides, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Any of these materials, any other material disclosed herein, or any other suitable material may be used to manufacture cap portion **28**. Even though it is disclosed above that cap portion **28** may be a lubricious material (and that core portion **26** may be a generally non-lubricious material or another material), this is not intended to be limiting. For example, in some embodiments, core portion **26** may include a lubricious material and cap portion **28** may be "non-lubricious".

A number of alternative surface characteristics and other modifications may be incorporated into shaft **24** via cap portion **28**. For example, cap portion **28** may be made from a material that provides increased chemical and/or thermal resistance, changes in hardness, adds radiopacity, increases or decreases MRI compatibility, or the like. For example, cap portion **28** may include a polymer doped with gold, platinum, palladium, tantalum, tungsten alloy, or another radiopaque material so as to define a surface with increased radiopacity. In at least some embodiments, cap portion **28** may be configured to elute or otherwise deliver a pharmaceutical agent. For example, cap portion **28** may include a slow-release form of a drug (such as an anti-clotting drug, for example) that can help reduce clotting that might otherwise occur without the drug. Of course, this structure and use is not intended to be limiting to anti-clotting drugs as any drug may be substituted without departing from the spirit of the invention.

The aforementioned apparatuses **10**/**10'** and the illustrated shaft **24** describe how devices can be produced with discrete sections having a selectively modified surface. Thus, a portion of the exterior or interior of shaft **24** is defined by core portion **26**, and another portion of the exterior or interior of shaft **24** is defined by cap portion **28**. The relevant exterior or interior portions can have different surface characteristics. This feature may be desirable for a number of applications. For example, endoscopic retrograde cholangiopancreatography (ERCP) techniques utilize an endoscope where it is desirable to use a catheter shaft that has a lubricious exterior section suitable for being disposed in the working channel of the endoscope and a less lubricious or "tacky" distal tip with a lower hardness that is suitable for cannulation of the major duodenal papilla or for probing sphincters and other body orifices. In addition, cap portion **28** may also modify the flexibility of shaft **24** and, in some embodiments, act as a strain relief.

As stated above, shaft **24** can be a catheter shaft or another type or component of a medical device. Accordingly, shaft **24** may include a number of additional features. For example, shaft **24** may have one or more lumens defined therein such as a first lumen **30** and a second lumen **32** as best seen in FIGS. **3** and **4**. First lumen **30** may be used, for example, to infuse contrast media, pharmaceuticals, angioplasty balloon inflation media, and the like, or any other suitable material. Second lumen **32** may be used, for example, as a guidewire lumen. A number of additional uses for lumens **30**/**32** are contemplated.

FIGS. **3** and **4** also illustrate another feature of shaft **24**. By comparing FIG. **3** with FIG. **4** it can be seen that both sections have essentially the same outer diameter (e.g., in the range of about 0.02 to about 0.35 inches or so). This is because extruder **18** can be configured to produce shaft **24** having a variable composition while maintaining a constant outer diameter by coupling with a variable speed take-off unit. For example, extruder **18** may be configured so that as the amount of material from hopper **14** (i.e., the hopper that cap portion **28** is made from) that reaches the cross-head **16** (or the extrusion die) increases, the amount of material making up shaft **24** from hopper **12** (i.e., the hopper that core portion **26** is made from) proportionally decreases. This allows a constant outer diameter shaft **24** to be produced that may also have a constant wall thickness. However, this need not be the particular

arrangement. For example, other embodiments of shaft **24** may include one or more tapers as is commonly seen in the catheter art or that include changes in wall thickness.

Shaft **24** may also include a number of additional structural features commonly associated with catheters and similar medical devices. For example, shaft **24** could include an angioplasty balloon, and embolic protection filter, a stent and/or means for expanding or retrieving a stent, a radiopaque marker, etc. Moreover, shaft **24** may include additional sections or components coupled thereto including metallic or polymeric shafts. These other metallic components may include metals typically used in catheters such as nickel-titanium alloy, stainless steel, etc.

FIG. **5** illustrates an example catheter shaft **124** disposed in the working channel **132** of an endoscope **134**. This Figure illustrates the usefulness of cap portion **128** for use with endoscopes such as endoscope **134**. FIG. **5** depicts that cap portion **128** has a different exterior surface characteristic (i.e., lubricity) than core portion **126**. This arrangement allows shaft **124** to be easily manipulated when disposed within working channel **132**.

FIGS. **6**A-**12**B depict various shafts that include differing arrangements of cap and core portions. Each embodiment may include any of the features described above for similarly named or depicted structures. For example, FIG. **6**A illustrates shaft **224** having core portion **226** and a discrete cap portion **228** disposed away from the ends of shaft **224** much like shaft **24** as depicted in FIG. **2**. The one or more lumens that can be present in shaft **224** are shown in FIG. **6** as a singular lumen **236**. However, lumen **236** is shown in this manner for the purpose of simplification. It can be appreciated that shaft **224** could also be generally solid (i.e., without lumen **236**) or include more than one lumen. FIG. **6**B depicts shaft **224'**, which is similar to shaft **224** except that cap portion **228** is disposed along the interior surface (i.e., adjacent lumen **236**) of shaft **224'**.

FIG. **7**A is another example shaft **324** that includes core portion **326** and cap portion **328**. According to this embodiment, cap portion **328** may begin at some centralized location (i.e., not at the end) and extend toward the end of shaft **324**. In some embodiments, cap portion **328** may extend all the way to one end of shaft **324**. In some other embodiments, cap portion **328** can extend all the way across shaft **324** to both ends. FIG. **7**B depicts shaft **324'**, which is similar to shaft **324** except that cap portion **328** is disposed along the interior surface (i.e., adjacent lumen **336**) of shaft **324'**.

FIG. **8**A is another example shaft **424** that includes core portion **426** and multiple cap portions **428***a/b*. This embodiment illustrates that multiple cap portions **428***a/b* may be utilized for shaft **424** or any of the shafts disclosed herein. FIG. **8**B depicts shaft **424'**, which is similar to shaft **424** except that cap portions **428***a/b* are disposed along the interior surface of shaft **424'**.

Similarly, FIG. **9**A illustrates shaft **524** where the different cap portions **528***a/b* are spatially limited to a particular section of cap portion **526**. This later feature can be achieved, for example, by adding further control to the radial position to which cap portion **528** is disposed on. FIG. **9**B depicts shaft **524'**, which is similar to shaft **524** except that cap portions **528***a/b* are disposed along the interior surface of shaft **524'**.

FIG. **10**A similarly shows shaft **624** where cap portion **628***a* is radially limited to one section of core portion **626** (and extends therefrom toward the end of shaft **624**) whereas cap portion **628***b* is radially limited to another more centralized section of core portion **626**. FIG. **10**B depicts shaft **624'**, which is similar to shaft **624** except that cap portions **628***a/b* are disposed along the interior surface of shaft **624'**.

FIG. **11**A illustrates another example shaft **724** including core portion **726** and cap portion **728**. Here it can be seen that cap portion **728** may be coated or otherwise added onto a generally constant core portion **726**. Accordingly, cap portion **728** appears "raised" or otherwise projects outward from the exterior of core portion **726**. FIG. **11**B depicts shaft **724'**, which is similar to shaft **724** except that cap portion **728** is disposed along the interior surface of shaft **724'** and extend into lumen **736**.

Additionally, shaft **824**, depicted in FIG. **12**A, may include core portion **826** and a similarly configured cap portion **828**. Cap portion **828** may be raised along the exterior of core portion **826** and extend toward at least one of the ends of shaft **824**. FIG. **12**B depicts shaft **824'**, which is similar to shaft **824** except that cap portion **828** is disposed along the interior surface of shaft **824'** and extend into lumen **836**.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A catheter shaft, comprising:

a catheter shaft comprising a first portion, a second portion, and a third portion, the catheter shaft having a constant outer diameter;

wherein the second portion is positioned between the first portion and the third portion;

wherein the first portion includes a first material;

wherein the second portion includes a first layer of the first material disposed over a second layer of a second material such that the second layer of the second material defines an inner surface of the catheter shaft;

wherein the first material has a first surface characteristic and the second material has a second surface characteristic different from the first surface characteristic; and

wherein the first surface characteristic is more lubricious than the second surface characteristic.

2. The catheter shaft of claim **1**, wherein the first surface characteristic is harder than the second surface characteristic.

3. The catheter shaft of claim **1**, wherein the second surface characteristic is harder than the first surface characteristic.

4. The catheter shaft of claim **1**, wherein the second material defines a first cap portion along the second portion of the catheter shaft.

5. The catheter shaft of claim **4**, wherein the second portion includes a second cap portion longitudinally spaced from the first cap portion.

6. The catheter shaft of claim **4**, wherein the first cap extends into a lumen of the catheter shaft.

7. The catheter shaft of claim **1**, wherein the first material defines a first layer disposed about an entire outer circumference of catheter shaft.

8. The catheter shaft of claim **1**, wherein the first material defines a first layer extending about only a portion of an outer circumference of the catheter shaft.

9. The catheter shaft of claim **1**, wherein the third portion includes the first material and is free of the second material.

10. The catheter shaft of claim **1**, wherein the catheter shaft comprises at least one lumen defined therein.

11. A medical device, comprising:

a catheter shaft having a first portion and a second portion;

wherein the first portion and the second portion are seamlessly connected and have the same outer diameter;

wherein the first portion includes a first material;

wherein the second portion includes a first layer of the first material and a second layer of a second material;

wherein the first material has a first surface characteristic and the second material has a second surface characteristic different from the first surface characteristic; and

wherein the first material is more lubricious than the second material.

12. The medical device of claim **11**, wherein the first layer of the first material defines an inner surface of the catheter shaft and the second layer of second material is disposed over the first layer of the first material.

13. The medical device of claim **11**, wherein the first layer of the first material defines an exterior surface of the catheter shaft and is disposed over the second layer of the second material, wherein the second layer of the second material defines an inner surface of the catheter shaft.

14. The medical device of claim **11**, wherein the second layer of the second material is disposed over the first layer of the first material and extends about the entire circumference of the catheter shaft.

15. The medical device of claim **11**, wherein the second layer of the second material is disposed over the first layer of the first material and extends about only a portion of the catheter shaft.

16. The medical device of claim **11**, wherein the second layer of the second material comprises two or more discrete segments, the two or more discrete segments including a first segment longitudinally space apart from a second segment along the catheter shaft.

17. The medical device of claim **16**, wherein the second layer of the second material is disposed over the first layer of the first material, wherein the first layer of the first material defines an inner surface of the catheter shaft.

18. A medical device, comprising:

a catheter shaft having a first portion and a second portion;

wherein the first portion and the second portion are seamlessly connected and have a constant wall thickness;

wherein the first portion includes a first material;

wherein the second portion includes a first layer of the first material and a second layer of a second material;

wherein the first material has a first surface characteristic and the second material has a second surface characteristic different from the first surface characteristic; and

wherein the first layer is more lubricious than the second material layer.

19. The medical device of claim **18**, wherein the first layer of the first material defines an exterior surface of the catheter shaft and is disposed over the second layer of the second material, wherein the second layer of the second material defines an inner surface of the catheter shaft.

20. The medical device of claim **18**, wherein the first portion and the second portion have a same outer diameter.

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